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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,451

07/18/2007

Domenico Fanara

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02/25/2009

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EXAMINER

THOMAS, TIMOTHY P

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

02/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,451	Applicant(s) FANARA ET AL.	
	Examiner TIMOTHY P. THOMAS	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-10,12-15 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) 6-10,14,15 and 18-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,12 and 17 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/18/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicants' arguments, filed 11/19/2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. Applicant's comments with respect to the Oath/Declaration are noted along with the inventor's signature next to the corrections. The objection to the Oath/Declaration is withdrawn.
3. Applicant's arguments with respect to the rejection of claims 1-2, 5, 12 and 17 under 35 USC 103 have been considered but are moot in view of the new ground(s) of rejection.

Claim Objections

4. Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

The use of the genus term p-hydroxybenzoate esters in a dependent claim, dependent on the independent claim that is limited to a combination of two species within the genus term broadens the subject matter with respect to the paraben compounds of claim 5.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-2, 5, 12, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is necessitated by the claim amendment

The use of the genus term p-hydroxybenzoate esters in claim 5, dependent on the claim 1 that is limited to a combination of two species within the genus does not make clear whether the genus term is an attempt to broaden the subject matter with respect to the paraben compounds of claim 1 or is a shorthand notation referring to the combination of the two paraben compound species recited in claim 1; therefore it is not clear what the scope of the instant claims is with respect to which paraben compounds are required.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-2, 5, 12, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLongueville et al. (WO 02/47689 A2; IDS 12/18/2008 reference); and Doron et al. ("Antibacterial effect of parabens against planktonic and biofilm *Streptococcus sobrinus*"; 2001 International Journal of Antimicrobial Agents; 18: 575-578).

This rejection is based on a reference file in the 12/18/2008 IDS.

DeLongueville teaches the use of an individual optical isomer of cetirizine for preparing a medicament (abstract); such optical isomers include levocetirizine, which contains preferably at least 95% by weight of the levocetirizine (p. 1, lines 29, 32-33); pharmaceutical compositions as liquid compositions in the form of a sterile solution miscible with water (p. 5, lines 12-13); carriers and diluents include water (p. 5, lines 21-22); preserving substances are taught (p. 5, line 15); topical application in the form of an aqueous solution (p. 5, line 30-31); solutions for oral administration (p. 6, lines 1-2); drops in the form of a liquid, with added preservatives (p. 6, lines 5, 7, 9); a syrup for oral formulation is preferred that contains methyl- and propylparaben (methyl parahydroxybenzoate and propyl parahydroxybenzoate) and purified water (p. 6, lines 18-20). DeLongueville does not a specific embodiment containing levocetirizine and the mixture of methyl parahydroxybenzoate and propyl parahydroxybenzoate (although each of these components is taught); or a total amount of methylparaben and propylparaben or their ratio present in the liquid composition.

Doron teaches the antibacterial effects of methyl and propyl paraben against *Streptococcus sobrium*, which is involved in tooth decay in the oral cavity, and that antibacterial synergistic effect was found between several combinations of parabens (abstract); at 0.03% (about 0.3 mg/mL) propyl paraben (PP), with increasing amounts of methyl paraben, decreasing amounts of viable bacterial counts were demonstrated (p. 577, Figures 1-2), the ratios vary from 0.015:0.03 (1:2) MP:PP to 0.25:0.3 (8.33:1), or almost 9/1. At the highest ratio in both figures no bacterial counts were recorded

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(Figures 1-2; pp. 576-575, bridging paragraph). Additionally, MP had the largest antibacterial effect of the parabens tested (abstract).

It would have been obvious to one of ordinary skill in the art at the time of the invention to select levocetirizine with methyl paraben and propyl paraben as preservatives for an aqueous oral formulation and to utilize a large excess of methyl paraben to propyl paraben, and to optimize the ratio and amounts while utilizing the minimum amount that gives satisfactory preservative effect, which would have given the compositions of the claims. The motivation to select levocetirizine would have been the recognized suitability of this compound for conditions responsive to cetirizine; the motivation to utilize and optimize the ratio and amounts would have been the routine optimization of conditions, recognizing synergistic effect is observed and minimizing the required amounts so as to minimize potential side effects of these components.

Conclusion

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 12/18/2008 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571)272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Timothy P Thomas/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614